REMARKS/ARGUMENTS

Reconsideration and continued examination of the above-identified application are respectfully requested.

By way of this Amendment, claims 1-6, and 8-11 have been amended. In particular, the claims have been amended to recite "a translation reaction solution" and the phrase "substances necessary for protein synthesis" has been further defined as "containing a substrate and an energy source." The remaining amendments are generally typographical or grammatical in nature. Full support for the amendments can be found throughout the present application, as explained herein, and the claims as originally filed. Accordingly, no questions of new matter should arise and entry of the amendment is respectfully requested.

Non-compliance under 35 U.S.C. §119(e)

At page 2 of the Office Action, the Examiner states that the applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e).

The applicants submit herewith a certified English-language translation of U.S. Provisional Application No. 60/542,201 and a statement that the translation is accurate. The applicants further confirm that this translation was filed in the provisional application, U.S. Patent Application No. 60/542,201. Accordingly, the applicants are entitled to the priority date of the provisional application.

Claim Objections

At page 4 of the Office Action, the Examiner objects to the claims, citing informalities. The claims have been amended to overcome the objections, as suggested by the Examiner.

Accordingly, these objections should be withdrawn.

Rejection of claims 1-6 and 8-11 under 35 U.S.C. §112, second paragraph

At pages 5-7 of the Office Action, the Examiner rejects claims 1-6 and 8-11 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This rejection is respectfully traversed.

The Examiner states that it is unclear what is meant by "low-molecular" in claims 1-4 and that the term "low-molecular" is not defined by the claims or the specification. The Examiner states that even if the term "low-molecular" refers to protein synthesis inhibitors of low molecular weight, the scope of the claim is unclear because it is not apparent what molecular weights or ranges of molecular weights would be considered "low." By way of this Amendment, claims 1-4 have been amended to recite "low-molecular weight" instead of "low-molecular." Further, low molecular weight synthesis inhibitions are defined in the present application as including molecular weights of not more than 50,000 and preferably not more than 14,000 (see e.g., page 15 of the present application).

The Examiner also states that the phrase "the substances necessary for protein synthesis" in claims 1-4, part (b), lacks antecedent basis. In response, the phrase "the substances necessary for protein synthesis" has been replaced with the phrase "substances necessary for protein synthesis containing a substrate and an energy source, and a specific translation template." Support for this amendment can be found, for instance, at page 6, lines 25-27 of the present application.

The Examiner further states that in part (b) of claims 1-4, the phrase "the well mentioned in "a"," lacks antecedent basis because part (a) of the claims refers to "each different well." The

Examiner states that there is ambiguity as to which of the multiple wells is intended by the reference to "the well." In response, the phrase "each different well" in claims 1-4 has been replaced with the phrase "one or more different wells."

The Examiner states that parts (a) and (b) of claims 1-4 are indefinite because they invoke process steps in the context of product claims. The process steps have been removed from claims 1-4.

The Examiner states that claims 2-4 recite the limitation "the protein" and that there is insufficient antecedent basis for this limitation. The claims have been amended to provide proper antecedent basis for "the protein".

The Examiner states that there is insufficient antecedent basis for the limitation "the solution in the well mentioned in "b" . . ." in claims 1-4. The phrase "the solution in the well mentioned in "b" has been removed from the claims.

The Examiner states that the limitation in claims 2-4 that the amount of deliquescent substance is "0.01 part by weight or less to 1 part by weight of the protein" is indefinite because the scope of the claims is not clearly set forth. The claims have been amended to recite "less than 0.01 part by weight".

The Examiner also states that the reference to "the protein" is unclear. The Examiner states that there is insufficient antecedent basis for this limitation as there is no prior mention that the reagent contains a protein. The claims have been amended to recite that the reagent does comprise a protein, to provide antecedent basis for "the protein".

The Examiner states that claims 3-4 refer to a "different kind type of translation template." The Examiner states that this terminology is vague and indefinite as the claims do not define what would be considered a "different" template. The claims have been amended to recite that a plurality

of different translation templates are contained in each of the different wells of the containers.

The Examiner states that the recitation in claim 4 of "said modification for fixation" lacks antecedent basis because although the claim refers to the protein being "modified for fixation," there is no recitation of a modification per se. The Examiner states that claims 4-5 are indefinite because claim 4 recites that the protein is "modified for fixation" and is also "coated." The Examiner states that this language is vague and indefinite and it is unclear what is meant. Claim 4 has been amended to recite that protein is modified for fixation to a well and/or carrier, the well and/or carrier being coated with a substance having affinity for the protein that is modified for fixation.

The Examiner then states that the recitation in claim 5 "selected from making into" is unclear. The Examiner states that it is unclear whether the protein is modified by attachment to avidin, biotin, or, alternatively, whether the protein is being modified by attachment to a substance having affinity to one of these species. Claim 5 has been amended to recite that the modifications for fixation is at least one which is selected from avidinylation, biotinylation, streptavidinylation, and His tag.

Accordingly, this rejection should be withdrawn.

Rejection of claims 1, 2, 6, and 8 under 35 U.S.C. §102(a) or §102(e) – Kuroita et al.

At page 8 of the Office Action, the Examiner rejects claims 1, 2, 6, and 8 under 35 U.S.C. §102(a) or, in the alternative, under 35 U.S.C. §102(e), as being anticipated by Kuroita et al. (U.S. Publication Application No. 2003/0199076 A1). The Examiner states that Kuroita et al. teaches a reagent recomposition for cell-free protein synthesis that is provided in a freeze-dried state for stability (referring to the abstract and paragraphs [0001], [0004], [0006], and [0102]). The

Examiner states that Kuroita et al. teaches that the reagent composition contains a cell extract, which may be from wheat embryo without endosperm and almost free of protein synthesis inhibitors, such as ribosome specific glycosidase (paragraphs [0003], [0035], [0055], and [0111]). The Examiner states that the composition contains a bioactive protein for cell-free protein biosynthesis, an energy source, template mRNA, substract amino acids, etc., which may be provided in kit form (paragraphs [0002], [0027], [0062], [0064], and [0089]-[0098]). With respect to claim 2, the Examiner states that Kuroita et al. teaches that the reagent composition includes an amount of a deliquescent material that is no more than 0.01 part by weight per part of protein (paragraphs [0011], [0024], [0034], and [0102]). With respect to claims 6 and 8, the Examiner states that Kuroita et al. teaches kits comprising the reagent composition (paragraphs [0089]-[0091]). This rejection is respectfully traversed.

As discussed in the present application, a ready-made preparation containing a cell extract for protein synthesis is desirable for high throughput protein synthesis (page 2, lines 15-19). In the past, such ready-made preparations did not include a translation template. The translation template was added before expression of the protein in order to analyze the interaction of many samples with the specific protein, and because a translation template, such as mRNA, is very unstable (page 3, line 23- page 4, line 3). The present inventors have found that protein can be synthesized in a simple operation in a micro-titer plate using a ready-made preparation that also includes mRNA. The ready-made preparation comprises a translation reaction solution, comprising substances necessary for protein synthesis, a translation template, and a stabilizer, are added to a solution containing a cell extract for cell-free protein synthesis. The resulting preparation is then freeze-dried in a well of a micro-titer plate. Using the reagent of the present invention, it is possible to synthesize one or more proteins in a highly efficient manner by only

adding a buffer containing a deliquescent substance to a dissolved cell-free protein synthesis composition.

The composition of Kuroita et al., however, much like conventional "ready-made" preparations for cell-free protein synthesis, does not include mRNA. The composition of Kuroita et al. simply includes an enzyme to produce mRNA (para. [0062]). As described in the present application, use of such preparations increases operation time and decreases efficiency because mRNA is to be prepared upon each use of the ready-made preparation. As such, the composition described in Kuroita et al. is not the same as the claimed invention.

Accordingly, this rejection should be withdrawn.

Rejection of claims 3-5 and 9-11 under 35 U.S.C. §103(a) -- Kuroita et al. in view of He et al. and Zuk et al.

At pages 9-11 of the Office Action, the Examiner rejects claims 3-5 and 9-11 under 35 U.S.C. §103(a) as being unpatentable over Kuroita et al. in view of He et al. (WO 02/14860) and Zuk et al. (U.S. Patent No. 4,208,479). The Examiner states that Kuroita et al. fails to specifically teach the use of multiple, different templates so that the protein chip reagent can be used to synthesize multiple, different proteins. The Examiner also states that with respect to claims 4-5, Kuroita et al. also fails to specifically teach attachment substances to the nascent proteins for the intended purpose of fixation or immobilization on a solid phase. The Examiner states that He et al. teaches cell-free protein synthesis systems that employ an array format, allowing the advantage of handling and investigation of multiple samples (pages 1 and 7-8). The Examiner also states that it would have been obvious to combine the template(s) with other components because Zuk et al. teaches that in performing assays, it is a matter of substantial convenience, as well as providing

significant enhancement in accuracy, to provide the reagents combined in a kit form and preferably in a single vessel (col. 22, lines 21-44). The Examiner states that it would have been obvious, therefore, to include the protein chip reagent of Kuroita et al., He et al., and Zuk et al. as part of a kit for the art-recognized benefits of convenience and commercial sale. This rejection is respectfully traversed.

Using the claimed invention, protein synthesis can be easily carried out by only adding a buffer containing a deliquescent substance to a protein synthesis composition dissolved in a well of a protein chip. Also, according to the present invention, many different types of proteins can be expressed in one well.

As described previously, the composition of Kuroita et al., like conventional "ready-made" preparations for cell-free protein synthesis, does not include mRNA and cannot be used in the manner described for the claimed invention. This deficiency in Kuroita et al. cannot be overcome by relying on the teachings of He et al. because He et al. does not describe freeze-dried preparations for cell-free protein synthesis. He et al. describes in vitro synthesis using a cell free system for transcription and translation, followed by immobilization of the products in a gridded format on a surface. In He et al. the transcription templates are prepared just prior to the transcription/translation reaction (pages 11-12). He et al. does not teach or suggest any freeze-dried preparations for carrying out protein synthesis, let alone, a freeze-dried preparation for cell-free protein synthesis comprising a translation template. Thus, combining the teachings of He et al. with Kuroita et al. would not allow one of ordinary skill in the art to arrive at a freeze-dried or "ready made" for cell-free protein synthesis, as presently claimed.

The Examiner also relies on Zuk et al. for its teaching that reagents can be combined in a kit form and in a single vessel. It is noted, however, that the "critical inquiry" in combining

various prior art references is whether there is something in the prior art as a whole that suggests the desirability of combining those references. Zuk et al. relates to reagents for immunoassays employing as reagents a labeled receptor. Zuk et al. does not relate to cell-free protein synthesis compositions. Given that Kuroita et al. and Zuk et al. are not related, they do not suggest the desirability, and thus the obviousness to be combined.

Even if Kuroita et al. and Zuk et al. could be properly combined, however, one of ordinary skill in the art would not arrive at the claimed invention. Zuk et al. does not teach or suggest a freeze-dried cell-free protein synthesis composition comprising a translation template. As such, Zuk et al. does not overcome the deficiencies noted in Kuroita et al.

Accordingly, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

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